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IN THE
Supreme Court of the United States

October Term, 1978

No. 78-1850
No. 79-5049

JAMES ROBERT PRIVITERA, JR.
Petitioner,

v.

THE STATE OF CALIFORNIA,
Respondent.

No. 78-1850

WILLIAM DAVID TURNER, et al.,
Petitioners,

v.

THE STATE OF CALIFORNIA,
Respondent.

No. 79-5049

ON PETITION FOR A WRIT OF CERTIORARI
TO THE SUPREME COURT OF CALIFORNIA

RESPONDENT'S BRIEF IN OPPOSITION

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RESPONDENT'S BRIEF IN OPPOSITION

The respondent, the State of California, respectfully requests that this Court deny the petition for a writ of certiorari, seeking review of the California Supreme Court's opinion in this case. That opinion is reported at 23 Cal.3d 697 (153 Cal.Rptr. 431, 591 P.2d 919).

JURISDICTION

This Court has jurisdiction to consider this case pursuant to 28 U.S.C. 1257, subdivision 3.

QUESTION PRESENTED

Does California Health and Safety Code section 1707.1, which prohibits the sale, prescription or administration of an untested and unproven cancer treatment, infringe on the right of privacy protected by the United States Constitution?

STATEMENT OF THE CASE

On October 3, 1974, the San Diego County, California, Grand Jury returned a three count indictment against petitioners, as well as one Eli Von Pinoci. In count I, all were charged with conspiracy to violate California Health and Safety Code section 1707.1, the sale of drugs, compounds or devices for the alleviation or cure of cancer, all in violation of California Penal Code section 182, subdivision (1). Fifty-two overt acts were alleged against the various defendants. In count II petitioner Davis was charged with unlawfully selling a drug and compound to be used in the treatment, alleviation and cure of cancer in violation of California Health and Safety Code section 1707.1. In count III, petitioners Turner and Davis were also charged with a violation of California Health and Safety Code section 1707.1. (1 CT 1-7.)

On October 8, 1974, petitioners Davis and Turner were arraigned in the San Diego County Superior Court. Petitioner Disney was arraigned on October 11, 1974,

while petitioner Privitera was arraigned on October 22, 1974. All petitioners entered pleas of not guilty to the charges. (IV CT 666-667, 669-671.)

Petitioners' demurrer to the indictment was heard on November 21 and 22, 1974, and denied by written opinion on January 2, 1975. (II CT 244-259; IV CT 683-687, 693.) A request for a rehearing on the demurrer was denied on January 23, 1975. (IV CT 704.)

On March 7, 10 and 11, 1975, petitioners' pretrial motions pursuant to Penal Code sections 995 and 1538.5 were heard by the court. (IV CT 710-713.) On March 18, 1975, the motions were denied. (IV CT 714.)

Petitioner Disney filed a motion to dismiss the indictment on the grounds of violation of a prior plea bargain and double jeopardy. (II CT 256; IV CT 714.) The motion was heard on April 15, 1975, and denied on June 12, 1975. (IV CT 732, 735.)

Petitioners Turner, Davis and Disney filed motions for severance and separate trials on July 8, 1975. (IV CT 738-740.) The motions were denied. (IV CT 742.)

Petitioners' jury trial began on July 29, 1975. (IV CT 743.) The prosecution's motion to dismiss count II as to petitioner Davis was granted by the trial court on October 9, 1975. (VII RT 372-376; IV CT 783.) On December 16, 1975, the jury returned its verdicts finding all of the petitioners guilty as charged in count I (conspiracy) and finding petitioners Turner and Davis guilty as charged in count III (sale of drug and compound to be used in the alleviation and cure of cancer). (II CT 417-423; IV CT 810-811.)

Petitioners' motion for a new trial was denied. (IV CT 814.) On February 2, 1976, petitioners were sentenced. Each petitioner was granted probation on certain terms and conditions. (III CT 588-592; IV CT 816.)

Each petitioner filed a timely notice of appeal. (III CT 593, 595, 611, 614, 665.) On November 10, 1977, the Court of Appeal, in a published opinion, reversed all of the convictions. However, on March 15, 1979, the California Supreme Court upheld the convictions of petitioners. Petitioners' petition for a rehearing was denied on April 12, 1979.

STATEMENT OF FACTS

The California Supreme Court aptly summarized the voluminous evidence presented at petitioners' trial.

> ". . . the evidence amply supports the jury's conclusion that defendants were involved in a common plan to import, prescribe, sell and distribute laetrile (also referred to as amygdalin or vitamin B-17) to cancer patients. Dr. Privitera prescribed laetrile for cancer patients and referred his patients to Turner and Disney as suppliers of laetrile. Disney referred patients to Dr. Privitera for treatment. Leslie and Disney worked as distributors in various residential areas. Defendants told prospective users that laetrile is an effective treatment or cure for cancer. Laetrile has not been approved for that purpose by one of the designated governmental agencies." (People v. Privitera, supra, at p. 701 [153 Cal.Rptr. at p. 433, 591 P.2d at p. 921].)

REASON FOR DENYING THE PETITION FOR A WRIT OF CERTIORARI

THE CALIFORNIA SUPREME COURT'S DECISION THAT PREMARKET REQUIREMENTS OF DEMONSTRATED SAFETY AND EFFICACY FOR ANY CANCER TREATMENT DO NOT IMPERMISSIBLY INVADE AN INDIVIDUAL'S RIGHT OF PRIVACY, IS SQUARELY IN ACCORD WITH THE HOLDINGS OF THIS COURT

California Health and Safety Code section 1707.1 prohibits anyone from selling, delivering, giving away or prescribing any drug, medicine, compound or device for the diagnosis, treatment, alleviation or cure of cancer unless the item involved has been approved under either section 505 of the Federal Food, Drug and Cosmetic Act or by the State of California. In order to obtain approval for the item in question, the basic showing which must be made according to rigorous scientific proof, is that the item is both safe and effective for the use intended. (Calif. Health & Safe. Code, § 1707.1, subds. (a)-(f); 21 U.S.C. 355(d).) Relying on three decisions of this Court, Planned Parenthood v. Danforth (1976) 428 U.S. 52, Roe v. Wade (1973) 410 U.S. 113, and Whalen v. Roe (1977) 429 U.S. 589, the California Supreme Court ruled that Health and Safety Code section 1707.1 bore a reasonable relationship to the legitimate state interest in the health and safety of its citizens, and ruled that the choice of medical alternatives selected from the commercial medical marketplace is not a decision within the zone of constitutionally protected privacy. The California Supreme Court's decision is squarely in line with the holdings of this Court. Since the California

Supreme Court correctly decided the issue, the petition for a writ of certiorari should be denied.

In a series of cases, and on the basis of a variety of theories, this Court has accorded some privacy protection to individual decision making with respect to whether to conceive or to bear a child. (Griswold v. Connecticut (1965) 381 U.S. 479; Eisenstadt v. Baird (1972) 405 U.S. 438; Roe v. Wade, supra, 410 U.S. 113; Doe v. Bolton (1973) 410 U.S. 179; Planned Parenthood v. Danforth, supra, 428 U.S. 52; Carey v. Population Services Int. (1977) 431 U.S. 678.) But, in none of these cases did this Court find that a decision among medical treatments (medical devices, drugs or procedures) fell within the right to privacy, so as to subject state regulation of the available treatment alternatives to constitutional evaluation under a compelling interest test.[1] On the contrary, where a choice of medical alternatives has been involved, this Court has always judged the validity of state regulation under the "rational basis" test.[2] Because California Health and Safety Code section 1707.1, as applied to laetrile, is reasonably related to legitimate governmental purposes -- protection of the public health and protection

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1. Where, as here, the particular choice at issue does not fall within the fundamental right to privacy, a compelling state interest test is not applied. (See, e.g., Carey v. Population Services Int., supra, 431 U.S. 678, 686 (Court applied the compelling state interest test only after concluding that particular decision fell within the right to privacy).)

2. (See, e.g., Planned Parenthood v. Danforth, supra, 428 U.S. 52, 75-79.)

of the public against fraud -- its constitutionality is clear.[3]

In Roe v. Wade, supra, this Court, after an exhaustive review of the medical, religious, and legal history of attitudes toward abortion (410 U.S. at pp. 129-148), concluded that the decision whether to have an abortion fell within the right to privacy (id., at pp. 152-153), and that state regulation of the decision whether to have an abortion could be justified only on a showing of a compelling state interest (id., at p. 155). (See also Doe v. Bolton, supra.) Finding no compelling state interest to justify a total prohibition of the right to decide whether to have an abortion during the first trimester of pregnancy (id., at p. 163),[4] this Court struck down a state statute that prohibited abortions.

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3. This assertion in no way is meant to imply that should, for some reason, this Court choose to apply the compelling state interest test, the statute could not meet that standard as well.

4. Significantly, this Court based its conclusion that a compelling state interest in prohibiting abortions during the first trimester was absent on the fact that "mortality in abortion" during that period "may be less than mortality in normal childbirth." (410 U.S. at p. 163.) While it cannot be claimed that legitimate methos of cancer therapy will be successful in all cases, it is equally clear that delay in seeking such therapy, and avoidance of it altogether, among patients using laetrile for treatment or prevention, has the certain result of increasing cancer mortality. (See, 42 Fed.Reg. at 39769, 39805-39806.) The terms safe and effective, as applied to legitimate cancer therapy, accordingly, are used in a relative sense.

But, notwithstanding the right to privacy found to exist in the general decision whether to have an abortion, this Court also held that there is no privacy right with respect to the choice of a particular medical or surgical procedure by which an abortion may be carried out. This Court held that, after the first trimester ". . . a State may regulate the abortion procedure to the extent that the regulation reasonably relates to the preservation and protection of maternal health." (410 U.S. at p. 163, emphasis added.)[5]

This "reasonable relation" standard is the normal rationality standard that applies to any statute. It is not the "compelling interest" standard that protects the right to privacy. Thus, even though the general decision to have an abortion is within the constitutional protection of privacy, state regulations of particular abortion procedures in the commercial medical marketplace are to be sustained if they reasonably relate to health protection. Such "reasonable regulation," of course, is permissible even where the pregnant woman is fully aware of the risks of late abortion and is willing to take them. Thus,

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5. In Doe v. Bolton, supra, 410 U.S. 179, this Court invalidated a requirement that abortions, unlike other medical or surgical procedures, be performed only at a hospital accredited by the AMA. (Id., at pp. 193-195.) This Court employed a "rational basis" test and found that the AMA accredidation requirement was not "reasonably related" to "the objective the State seeks to accomplish," protection of maternal health, because other "appropriately licensed institutions, satisfy these health interests." (Id., at pp. 194-195.)

the state can protect a pregnant woman's own health even against her wishes (although it cannot prohibit abortions altogether). Indeed, in Roe v. Wade, this Court held that a state, without trenching on any right to privacy, can further its important interests "in the areas of health and safety" by requiring that abortions be performed only at licensed institutions which "insure maximum safety for the patient" and may prohibit any abortion performed by a person not a physician, as defined by state law. (410 U.S. at pp. 149, 150, 165.)[6]

Illustrative of the principle that the choice among medical alternatives incidental to the exercise of some fundamentally protected right is not itself a

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6. If, as the petitioners imply, the constitutional right to privacy attached to all decisions relating to health care, a state could not lawfully require that medical procedures be performed by licensed practicioners only; the licensing requirement, as applied to the provider of medical services, restricts patient options in making health care decisions, just as the prohibition of laetrile under the Health and Safety Code also restricts patient options. It is, of course, well settled, as this Court recognized in Roe v. Wade, supra, that states constitutionally may restrict the practice of medicine to those licensed by state law. (Douglas v. Noble (1923) 271 U.S. 165; Garcia v. Texas State Board of Medical Examiners (W.D.Tex. 1974) 384 F.Supp. 434 (three judge court); England v. La. State Board of Medical Examiners (E.D.La. 1965) 246 F.Supp. 993, aff'd (1966) 384 U.S. 855.) And, the states have broad police powers in regulating the administration of drugs by the health professions. (Robinson v. California (1962) 370 U.S. 660, 664-665; Whipple v. Martinson (1921) 256 U.S. 41, 45.)

decision within the zone of constitutionally protected privacy is this Court's recent holding in Planned Parenthood v. Danforth, supra. There, this Court struck down a state prohibition of a particular abortion procedure, saline amniocentesis. (428 U.S. at p. 79.) However, this Court did not hold that the prohibition violated any right to privacy. This Court also did not hold that because the right to privacy encompasses a woman's decision whether to have an abortion, the state therefore may not prohibit a particular abortion procedure. Rather, citing Roe v. Wade, supra, 410 U.S. at page 164, This Court stated the issue before it as follows: "[W]hether the flat prohibition of saline amniocentesis is a restriction which 'reasonably relates to the preservation and protection of maternal health.'" (428 U.S. at p. 76, emphasis added.) This Court cited voluminous record evidence of the safety and effectiveness of saline amniocentesis, as compared with other available abortion procedures, and concluded that the state prohibition bore no reasonable relationship to protection of maternal health. (428 U.S. at p. 76.) Significantly, in discussing the validity of the statutory prohibition of this particular medical procedure, this Court did not refer to any constitutional consideration of privacy. No such considerations were involved in the selection of that particular medical procedure by the patient and her physician. The procedure was evaluated by them and by this Court solely on the basis of medical evidence of its safety and effectiveness. (428 U.S. at pp. 75-79.)

Thus, as the California Supreme Court correctly noted,

> "Planned Parenthood thus stands for the proposition that although the decision to have an abortion may be within the constitutional zone of privacy deserving the protection provided by the compelling interest standard, the selection of a particular procedure is a medical matter to which privacy status does not attach and which may be regulated by government, providing a rational basis for such regulation exists." (People v. Privitera, supra, 23 Cal.3d at pp. 703-704 [153 Cal.Rptr. at p. 434; 591 P.2d at p. 922].)

The applicability of these principles to the instant case is clear. An individual is surrounded by a zone of privacy that permits him to make the fundamental decision of whether or not to seek medical treatment for his illness, cancer. However, once the individual has made his decision to seek treatment and ventures into the commercial medical marketplace, his zone of privacy diminishes. The state has the right to impose on that medical marketplace regulations which reasonably relate to the preservation and protection of its citizens. In this case the State of California has required a premarket demonstration of safety and efficacy, for any cancer treatment or cure. Such a state regulation is clearly proper.

The constitutionality of such government premarket regulations has been repeatedly upheld by this Court. (Weinberger v. Hynson, Westcott & Dunning (1973) 412 U.S. 609, 629-630; Ciba Corp. v. Weinberger (1973) 412 U.S. 640, 643-644.) Indeed, just last term this Court upheld the federal premarket requirements of safety and efficacy as applied to laetrile. (United States v. Rutherford (June 18, 1979) 99 S.Ct. 2470, ___ U.S. ___.)

Such food and drug laws are designed to protect "the public health and pocketbook against adulterated and misbranded drugs" and this objective "has led court to declare with

unanimity that food and drug legislation should be given a liberal construction in order to accomplish its remedial purposes." (United States v. 7 Jugs, etc. of Dr. Salsbury's Rakos (D.Minn. 1944) 53 F.Supp. 746, 752, citing several United States Supreme Court decisions.)

Speaking of the Federal Food, Drug and Cosmetic Act of 1938, this Court observed in United States v. Dotterweich (1943) 320 U.S. 277 at page 280,

> "
> "The purpose of this legislation . . . touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words." (Id., emphasis added.)

The Dotterweich case was cited, quoted from and strongly reaffirmed in United States v. Park (1975) 421 U.S. 658, 668-669.

Thus, there can be no question that the California Supreme Court correctly determined that a premarket demonstration of safety and efficacy for a cancer treatment or cure reasonably relates to the proper goal of preservation and protection of the health of California citizens. Thus, the California Supreme Court's decision was in line with this Court's holdings concerning premarket requirements for drugs as well.

Finally, it should be noted that throughout the petition is the premise that the use of laetrile is harmless and nontoxic. (Privitera Petition, pp. 13, 15, 17.) That

issue was not addressed by the opinion of the California Supreme Court and thus normally will not be reviewed by this Court. (NLRB v. Sears, Roebuck & Co. (1975) 421 U.S. 132, 163-164.) Moreover, as aptly noted by amicus curiae, The American Cancer Society, in its opposition to the petition for a writ of certiorari, such an assertion is simply wrong. (See Amicus Opposition, pp. 12-14.)

CONCLUSION

The sole ground offered by the petitioners for the granting of the petition for a writ of certiorari was an alleged error by the California Supreme Court in construing the decisions of this Court relating to the right to privacy. However, a careful examination of the ruling of the California Supreme Court rendered in the case at bar establishes that that decision is in complete accord with the holdings of this Court. Thus, the decision rendered below is correct, California Health and Safety Code section 1707.1 does not violate any right of privacy protected by the Federal Constitution, and the petition for a writ of certiorari should be denied.

Respectfully submitted,

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